

Food and Drug Administration, HHS

§ 861.38

developers other than Federal agencies.

(c) Maintain records disclosing the course of development of the proposed standard, the comments and other information submitted by a person in connection with such development (including comments and information regarding the need for a standard), and such other information as may be required to evaluate the standard.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

§ 861.34 Amendment or revocation of a standard.

(a) The Food and Drug Administration will provide for periodic evaluation of performance standards to determine whether such standards should be changed to reflect new medical, scientific, or other technological data.

(b) The Food and Drug Administration may, on its own initiative or upon petition of an interested party, amend or revoke by regulation a standard established under this part.

(c) Any petition to amend or revoke a standard shall:

(1) Identify the specific device and standard for which the amendment or revocation is sought; and

(2) Be submitted in accordance with the requirements of § 10.30.

(d) Proceedings to amend or revoke a performance standard shall be conducted in accordance with the rulemaking procedures of § 10.40. In addition, a notice of proposed rulemaking to amend or revoke a standard shall set forth proposed findings with respect to the degree of risk or illness to be eliminated or reduced and the benefit the public will derive from the proposed amendment or revocation.

§ 861.36 Effective dates.

(a) A regulation establishing, amending, or revoking a performance standard will set forth the date upon which it will take effect. To the extent practical, consistent with the public health and safety, such effective date will be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade.

(b) Except as provided in paragraph (c) of this section, no regulation establishing, amending, or revoking a stand-

ard may take effect before 1 year after the date of its publication unless:

(1) The Food and Drug Administration determines that an earlier effective date is necessary to protect the public health and safety; or

(2) The standard has been established for a device that, by the effective date of the standard, has been reclassified from class III to class II.

(c) The Food and Drug Administration may declare a proposed regulation amending a standard effective on publication in the FEDERAL REGISTER if it determines that making the regulation so effective is in the public interest. A proposed amendment of a performance standard made effective upon publication may not prohibit the introduction or delivery for introduction into interstate commerce of a device that conforms to the standard without the change or changes provided in the proposed amendment until the effective date of any final action on the proposal.

[45 FR 7484, Feb. 1, 1980, as amended at 57 FR 58405, Dec. 10, 1992]

§ 861.38 Standards advisory committees.

(a) The Food and Drug Administration will establish advisory committees to which proposed regulations may be referred, and these committees shall consider such referrals in accordance with this section and part 14 of this chapter. Such advisory committees, which may not be classification panels, shall be considered ad hoc advisory committees. Their members shall be selected in accordance with §§ 14.82 and 14.84, except that no member may be a regular full-time FDA employee. Each advisory committee established under this section shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry.

(b) A proposed regulation to establish, amend, or revoke a performance standard shall be referred to an advisory committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment if: